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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,976	08/09/2006	Fredrik Joabsson	613-102	2888

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,976	JOABSSON ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, 10-14, 16-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al (USPN 6,066,328 hereafter '328).

The '328 patent teaches a amphiphillic composition comprising an active agent and a method of making said formulation (abstract). The formulation is a colloidal milk, cream or gel form (col. 6, lin. 16-18). The formulation comprises an amphiphillic lipid, active agent, and surfactant with HLB up to 12 (col. 3, lin. 30-35, col. 4, lin. 29-50). The components are mixed forming a dispersion of the active agent, followed by heating the mixture to a temperature from 20-95 ^{o}C from 10-60 minutes (col. 6, lin. 30-35). The mixture is cooled to around room temperature (col. 7, lin. 1-25). The formulation comprises multiple amphiphillic compounds including oils, and surfactants (Examples). The formulation can comprise fragrances, perfumes and water as a carrier (col. 4, lin. 41, examples). Regarding the stability of the particles, it is the position of the Examiner that such limitations are functional and dependent from the compositional components of the particles. Since a composition and its properties cannot be separated, the same components must have the same properties. As such the prior art discloses amphiphillic particles comprising the same amphiphillic polymers and incorporated active agents, therefor their stability must also be the same.

Regarding claim 10, it is the position of the Examiner that the claim limitations reciting the incubation time and temperature are merely product by process limitation and do not overcome the prior art. The claim recites particles comprising an active agent incorporated into a particle comprising amphiphillic polymers. This limitation is a functional limitation that is dependent on the disposition of the amphiphillic compounds and the active agents, which are identical to those of the instant claims. Amphiphillic compounds are dispersed, and mixed with solutions of active agents at elevated temperature, and as such should result in the same drug loaded particles of the instant claims since the compounds are identical and they are disposed in an identical fashion. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For these reasons the claims are anticipated.

Claims 1-3, 6, 7, and 9-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Landh et al (USPN 5,531,925 hereafter '925).

The '925 patent teaches a method of making amphiphillic particles comprising forming a dispersion of particles comprising active agents and amphiphillic polymers at an elevated temperature and cooling the resultant mixture (claim 7-11). The particles are equilibrated at a temperature (37°C) followed by freeze-drying (col. 11, lin. 1-26). The particles are colloidal

(claims 16 and 17). The core of the particles is completely non-lamellar (claim 1). The particles further comprise fragmented compounds including, fatty alcohols, and block copolymers such as Poloxamer 188 with an HLB of 29 (col. 10, lin. 40-45, col. 16, lin. 15-45). The particles are included into pharmaceutical formulation comprising carriers and excipients (claim 19). Regarding the stability of the particles, it is the position of the Examiner that such limitations are functional and dependent from the compositional components of the particles. Since a composition and its properties cannot be separated, the same components must have the same properties. As such the prior art discloses amphiphillic particles comprising the same amphiphillic polymers and incorporated active agents, therefor their stability must also be the same.

Regarding claim 10, it is the position of the Examiner that the claim limitations reciting the incubation time and temperature are merely product by process limitation and do not overcome the prior art. The claim recites particles comprising an active agent incorporated into a particle comprising amphiphillic polymers. This limitation is a functional limitation that is dependent on the disposition of the amphiphillic compounds and the active agents, which are identical to those of the instant claims. Amphiphillic compounds are dispersed, and mixed with solutions of active agents at elevated temperature, and as such should result in the same drug loaded particles of the instant claims since the compounds are identical and they are disposed in an identical fashion. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For these reasons the claims are anticipated.

Response to Arguments

Applicant's arguments filed 3/18/10 have been fully considered but they are not persuasive. Applicant argues that:

(1) The '328 patent does not anticipate the claims since it does not disclose the method or dosage form as recited in the instant claims. Applicant argues that the '328 patent method has no particles present prior to the heat-fragmentation method, no active agent is incorporated by that method and no heating in a solution of active agent is disclosed.

(2) The '925 patent does not anticipate the claims since it does not disclose the method or dosage form as recited in the instant claims. Applicant argues that there is no heating and cooling step carried out on amphiphillic particles since particles do not exist prior to the heating-step. Also applicant argues there is no heat treatment carried out in a solution of active agents.

Regarding argument (1), it remains the position of the Examiner that the '328 patent continues to anticipate the instant claims. The '328 patent discloses a method of amphiphillic particles comprising forming a dispersion of particles and heating the mixture with an aqueous drug followed by cooling. This can be seen in the examples where phase A comprises amphiphillic compounds in dispersion with a particle size from 80-500 nm (col. 2, lin. 35-60). These particles are present before the heat treatment and inherent to the formulation (abstract). This is combined with an aqueous phase C comprising hydroxyproline (active agent) and heated to a temperature of 90° C and allowed to cool to room temperature (Example 3). This meets the

limitations of the claim by teaching a dispersion of particles (phase A) mixed with a solution of active agent (phase C). These disclosures render the claims anticipated.

Regarding argument (2), it remains the position of the Examiner that the '925 patent continues to anticipate the instant claims. The '925 patent teaches a method of forming an amphiphillic particles comprising forming a dispersion of amphiphillic particles (abstract, col. 16, lin. 15-26), followed by equilibrating said material in a solution of active agents (col. 10, lin. 9-25; col. 10, lin. 66-col. 11, lin. 11). This occurs at an elevated temperature of 37° C meeting the limitations of the claims. The particles are homogenized at room temperature (25° C) which is cooler than the equilibration temperature of 37° C. Regarding claim 10, it remains the position of the Examiner that the claim limitation do not distinguish the claim over the prior art. The claim recites particles comprising an active agent incorporated into a particle comprising amphiphillic polymers. This limitation is a functional limitation that is dependent on the disposition of the amphiphillic compounds and the active agents, which are identical to those of the instant claims. Amphiphillic compounds are dispersed, and mixed with solutions of active agents at elevated temperature, and as such should result in the same drug loaded particles of the instant claims since the compounds are identical and they are disposed in an identical fashion. Since the same products have been combined in the same fashion they must have the same features since product and their properties cannot be separated. For these reasons the claims remain anticipated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618